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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,076	03/02/2004	Elaine Lim	1001.1766101	4203
28075	7590	12/14/2005		EXAMINER
CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420				THANH, LOAN H
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/792,076	LIM ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	LoAn H. Thanh	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 02 March 2004.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-44 is/are pending in the application.  
 4a) Of the above claim(s) 5,12-16,20-27,30,36 and 40-44 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-4,6,8-11,17-19, 28,29,31,34,35 and 37 is/are rejected.  
 7) Claim(s) 7,32,33,38 and 39 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>06/10/04,07/19/04</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input checked="" type="checkbox"/> Other: <u>IDS 08/04/05</u> .

**DETAILED ACTION**

***Election/Restrictions***

This application contains claims directed to the following patentably distinct species of the claimed invention:

I/ figs. 1-3

II/ figs. 4-6

III/ figs. 7-9

IV/ fig. 4

V/ fig. 5.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1,28, 34 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with David Crompton on 12/09/05 a provisional election was made without traverse to prosecute the invention of species I , claims 1-4,6-11,17-19,28-29,32-35, and 37-39. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5,12-16,20-27,30,36,40-44 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

An action on the merits now follows.

***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 06/10/04, 07/19/04, 08/04/05 were filed before the first office action on the merits. The submission is in

compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4,6,8-9,17, 28-29,31,34-35 rejected under 35 U.S.C. 102(b) as being anticipated by Roberts et al. (USPN 5,545,209).

Roberts et al. disclose a balloon catheter comprising an elongated shaft 20 having a balloon 10 disposed at the distal region of the shaft, wherein the balloon has a first expansion configuration wherein the balloon first diameter is expanded in the distal portion and the proximal portion is in a collapsed configuration and a second expanded configuration where the first and second diameter of the expanded balloon is substantially the same. See figures 1-6. Specifically figure 3 and 6. Roberts et al. disclose a balloon catheter for insertion into a patient wherein the shaft comprises a multilumen catheter having an inflation lumen 21 and a guidewire lumen 19. The balloon proximal portion is releasably attached to the shaft by epoxy adhesive. The

term "releasably" or "releasable" is considered to be intended use. See columns 4, 6, 7-8, 12.

Claims 1-4,6,9,28-29, 34, 35, 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Briscoe et al. ( USPN 6,458,096).

Briscoe et al. disclose a balloon catheter having a balloon 46 disposed on the distal region of the shaft 14. The balloon is releasable at the distal portion of the balloon when the differential pressure is exceeded. See abstract, Figures 1-4, columns 2 and 5.

Claims 1-2, 28-29, and 34-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Musbach et al. (USPN 6,835,189).

Musbach et al. disclose a balloon catheter having a first expanded configuration with a first diameter and a proximal portion of the balloon collapsed. And a second configuration with the first and second diameter substantially the same. See figures 4 (first configuration) and 1 ( second configuration).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. ( USPN 5,545,209) in view of Stevens ( USPN 4,798,586).

Roberts et al. disclose the invention as substantially claimed. See above. Roberts et al. disclose a balloon catheter for insertion into a patient. Robert et al. is silent to the radiopaque markers disposed on the shaft. Stevens discloses a balloon catheter for insertion into a patient with radiopaque markers on the shaft for monitoring balloon catheterization procedure. See column 3, line 67 to col. 4 lines 1-2. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the shaft of Roberts et al. with radiopaque markers disposed on the shaft as taught by Stevens in order to provide monitoring and confirmation of the location of the balloon within the patient body. This would assist the physician to guide the balloon to the target location.

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. ( USPN 5,545,209) in view of Sugiyama et al. ( USPN 4,964,853).

Roberts et al. disclose the invention as substantially claimed. See above. Roberts et al. disclose a balloon catheter for insertion into a patient having a multilumen catheter comprising an inflation lumen 21 and a guidewire lumen 19. Robert et al. is silent to the specific configuration of the shaft as claimed. Sugiyama et al. disclose a balloon catheter for insertion into a patient having a multilumen configuration of the shaft comprising an inflation lumen and guidewire lumen. It would have been obvious to one of ordinary skill in the balloon catheter arts to modify the configuration of the multilumen catheter to be coaxial and elongated from the proximal to distal region as

claimed as a mere design choice performing equivalent functions to provide an inflation and guidewire lumen.

***Allowable Subject Matter***

Claims 7,32-33,38-39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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LoAn H. Thanh  
Primary Examiner  
Art Unit 3763

LT

12/09/05